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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,958	10/16/2001	Joseph J. Florio	A01P1073	7296
36802	7590	12/10/2004	EXAMINER	
PACESETTER, INC. 15900 VALLEY VIEW COURT SYLMAR, CA 91392-9221			FOREMAN, JONATHAN M	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 12/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/981,958

Applicant(s)

FLORIO ET AL.

Examiner

Jonathan ML Foreman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 2, 6, 8-18, 20 and 22-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-5, 7, 19 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/12/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1 - 36, drawn to a lead and device for delivering a lead, classified in class 600, subclass 585.
 - II. Claim 37, drawn to a method for implanting an endocardial lead, classified in class 607, subclass 119.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus does not include an introducer sheath as required by the process.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
5. During a telephone conversation with Derrick W. Reed on 12/1/04 a provisional election was made without traverse to prosecute the invention of a lead and device for delivering a lead, claims 1 - 36. Affirmation of this election must be made by applicant in replying to this Office

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action. Claim 37 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Additionally, Applicant's election without traverse of the Restriction/Election Requirement of 9/15/04 to Species II corresponding to Figure 5 in the reply filed on 9/27/04 is acknowledged. Applicant has asserted that claim 2 reads on Species II. However, claim 2 is directed to the V and VI species as shown in Figures 8 – 11 (See Page 12, lines 17 – 32). Accordingly, claim 2 has been withdrawn from consideration along with claims 6, 8-18, 20 and 22 – 36.

Information Disclosure Statement

The information disclosure statement filed 1/12/04 complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file, and the information referred to therein has been considered by the examiner as to the merits.

Specification

7. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

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8. The abstract of the disclosure is objected to because the length exceeds 150 words.

Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1, 3 – 5 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,714,823 to De Lurgio et al.

11. In reference to claims 1, 3 – 5 and 19, De Lurgio et al. discloses an implantable lead system (Figures 3 and 4) including a lead body (32) for placement in the coronary sinus region (Col. 3, lines 46 – 48), the lead body (32) having at least one electrode (28a, 28b) positioned at a distal end of the lead body, the distal end of the lead body including a distal tip (38), the lead further having a lumen (36) extending the length of the lead and communicating with an aperture in the distal tip (Col. 6, lines 45 – 49); and a device (42) dimensioned for insertion within the lumen (Col. 7, lines 12 – 15), the device including a main body formed of wire (Col. 7, lines 23 – 24); a steering knob (14) secured to a proximal extremity of the main body; and a flexible distal portion (44) formed of a wire coil separate from the main body secured to a distal extremity of the main body (Col. 7, lines 23 – 24), the main body having a length such that, with the main body of the device substantially completely advanced within the lead, the flexible distal portion of the device projects distally from the aperture in the distal tip of the lead body (Figure 8; Col. 8, lines 11 – 21).

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12. Claims 19 and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,383,146 to Klint.

In reference to claims 19 and 21, Klint discloses Applicant's claimed invention including a main body formed of wire (Col. 4, lines 59 - 61); a steering knob (5) secured to a proximal extremity of the main body; and a flexible distal portion formed of a wire coil secured to a distal extremity of the main body (Col. 5, lines 50 - 55) The wire coil comprising the flexible distal portion has an outer diameter smaller than that of the main body (Col. 5, lines 61 - 67).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 7 and 21 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,714,823 to De Lurgio et al. as applied to claims 5 and 19 above, and further in view of U.S. Patent No. 5,746,701 to Noone.

In reference to claims 7 and 21, De Lurgio et al. discloses a guiding member (Figure 4) having a main body and a flexible portion comprising a wire coil, but fails to disclose the wire coil having an outer diameter smaller than that of the main body. However, Noone discloses a guiding member having a main body (101) and a flexible distal portion comprising a wire coil (106; Col. 7, lines 2 - 3), where the outer diameter of the wire coil is smaller than that of the main body (Figure 10). It would have been obvious to one having ordinary skill in the art to modify the wire coil as

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disclosed by De Lurgio et al. to have an outer diameter smaller than that of the main body as taught by Noone in order to increase the flexibility of the distal portion relative to the main body.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent N.O. 4,381,013 to Dutcher.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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